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Barry N. Gellman

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MAYER & WILLIAMS PC
251 NORTH AVENUE WEST
2ND FLOOR
WESTFIELD, NJ 07090

EXAMINER

SHELL, LAURA C

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/757,159	Applicant(s) GELLMAN, BARRY N.	
	Examiner LAURA C. SCHELL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-20,22,23 and 26-38 is/are pending in the application.
- 4a) Of the above claim(s) 27 and 33-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-20,22,23,26,28-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of System Species A (Figs. 1, 2, 5) and Injectable Material Species 1 in the reply filed on 11/12/2008 is acknowledged. The traversal is on the ground(s) that the search would not prove to be a burden on the examiner. This is not found persuasive because the claimed subject matter may require searching in areas other than the medical area.

The requirement is still deemed proper and is therefore made FINAL.

Claims 27, 33-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/12/2008.

Claim 27 is being withdrawn as the claimed auger is not shown in the drawings, nor labeled in the specification as specifically being shown in one of the drawings. Applicant elected system species A which is Figs. 1, 2 and 5 and the specification only describes the mixing element 10 as being a mixing element, not specifically an auger.

Claim 33 is being withdrawn as it is drawn to the non elected injectable material species (bioactive molecule).

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Claim 34 is being withdrawn as the claim is drawn to the middle portion of the lumen having a larger diameter than the proximal portion of the lumen, which is shown in the non-elected Figs. 6a and 6b.

Claims 35-38 are being withdrawn as the claim is drawn to the mixing member being a screw. The specification discloses that mixing members of Figs. 3a-3e are labeled specifically as screws with threads, and Figs. 3a-3e are non elected species.

Claim Objections

Claim 29 is objected to because of the following informalities: claim 29 appears to be a duplicate of claim 28, as it depends directly from claim 28 and claims the exact same limitations. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 17, 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz-Feldman (US Patent No. 5,501,371). Schwartz-Feldman discloses a driving system for use with an injector system (Figs. 1-3 and 7-9; please note that the driving system needs only to be capable of use with the injector system that follows, as Applicant is claiming “a driving system” and the rest of the first

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paragraph of the claim is part of the preamble which the driving system needs only to be capable of use with), the injector system comprising: a housing (28) defining a lumen (22) and having an output end (near 36) and a driving system connection end (near 40); the lumen comprising a proximal portion (near 28) and a distal portion (near 86) and the inner diameter of the proximal portion being substantially larger than the inner diameter of the distal portion (the inner diameter at 28 is clearly larger than the inner diameter of the tapered portion of the distal end of the lumen at 40); a needle assembly (84) coupled to the output end of the housing (coupled at 36) for coupling to a needle; and a mixing member (Fig. 1, 26; col. 3, lines 36-37 disclose that the mixing means of the device is comprised of both element 100 and element 102) extending through the lumen from the driving system connection end to at least the output end (Fig. 1 discloses that the needle assembly connects at 36 and Fig. 1 also discloses that end portion 140a of the mixing member extends into the needle assembly. As disclosed above, col. 3, lines 36-37 disclose that the mixing member is comprised of both 100 and 102 and as disclosed in Fig. 3, the distal end of 102 includes 130, which is therefore also part of the mixing member as it is an integrally formed part of 102. Also, portions 100 and 102 are interconnected as seen in Figs. 1 and 6, in which the blades 108a, 108b and 108c extend through slots 132a, b and c of element 102. Therefore any rotation of the blades 108 is thereby transmitted to element 102 because of the connection, thus end portion 130 rotates with the rotation of elements 100 and 102. This is further disclosed by col. 4, lines 33-41 in which Schwartz-Feldman discloses that the blades 108 are in an intermediate position, labeled as 108a', b' and c', which is disclosed in Fig. 6, which

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further clearly discloses that the blades extend through the slits 132 thereby allowing the rotation connection between elements 100 and 102. Thus the distal end 130 rotates within the needle assembly as well.), the mixing member being rotatable within the lumen in both the proximal portion and the distal portion (Figs. 1-8 disclose that the mixing member rotates within both these portions); and the driving system (50; col. 4, lines 12-14 disclose that 50 is the member that does the driving and is therefore the driving system) comprises: a drive mechanism (50); an actuator (56) coupled to the drive mechanism to actuate the drive mechanism (56 are the flanges which the user would grip in order to actuate the drive mechanism 50); and a rotatable interfacing member (interfacing member is made of ribs 66a, 66b, 66c and 66d which are located on the inner surface of 62, since 62 rotates, ribs 66a-66d rotate as well and these couple to the notches 110a, 110b, 110c and 110d on the mixing member which cause the mixing member to rotate (col. 3, lines 40-43) coupled to the drive mechanism for coupling the mixing member to rotate the mixing member when the interfacing member is driven by the drive mechanism (col. 3, lines 40-43), wherein the mixing member is rotatable in the needle assembly and the lumen (Fig. 1 discloses that the mixing member 100 rotates within the lumen 22 as well as within the needle assembly, as end portion 130 of the mixing member extends within the needle assembly in Fig. 1, where the end portion of the needle assembly that connects to the housing is at 36. (Fig. 1 discloses that the needle assembly connects at 36 and Fig. 1 also discloses that end portion 140a of the mixing member extends into the needle assembly. As disclosed above, col. 3, lines 36-37 disclose that the mixing member is comprised of both 100 and

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102 and as disclosed in Fig. 3, the distal end of 102 includes 130, which is therefore also part of the mixing member as it is an integrally formed part of 102. Also, portions 100 and 102 are interconnected as seen in Figs. 1 and 6, in which the blades 108a, 108b and 108c extend through slots 132a, b and c of element 102. Therefore any rotation of the blades 108 is thereby transmitted to element 102 because of the connection, thus end portion 130 rotates with the rotation of elements 100 and 102.

This is further disclosed by col. 4, lines 33-41 in which Schwartz-Feldman discloses that the blades 108 are in an intermediate position, labeled as 108a', b' and c', which is disclosed in Fig. 6, which further clearly discloses that the blades extend through the slits 132 thereby allowing the rotation connection between elements 100 and 102. Thus the distal end 130 rotates within the needle assembly as well. Furthermore, the examiner would like to point out that there is no claim language stating where/at what location in the injector system that the mixing occurs. As the claim language currently reads, it only requires the mixing member to rotate in the needle assembly and the lumen, which as discussed above and as disclosed by Schwartz-Feldman, it clearly does).

In reference to claim 17, Schwartz-Feldman discloses that the driving system is capable of coupling to an injector system (Fig. 1), the injector system comprising a tubular member (28) and a mixing member (100) extending through the tubular member (Fig. 1).

In reference to claims 31 and 32, Schwartz-Feldman discloses that the injector system comprises an injectable material comprising a shear-sensitive injectable

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material (please note that this component is part of the injector system which is part of the intended use phrasing of the claim and therefore the driving system merely has to be capable of use with it, which it is. Also, the reference discloses that the device is used to mix dental impression material which changes viscosity as it is mixed and is then subjected to shear forces when being injected through the needle, which therefore meets Applicant's definition of a shear sensitive material).

Claims 18-20, 22, 23, 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Hicks (US Patent No. 2,825,134). Hicks discloses a coupling system (Fig. 1) for use with a tube of a syringe (the tubular portion of 10) comprising a proximal portion and a distal portion and the inner diameter of the proximal portion being substantially larger than the inner diameter of the distal portion (please note that this amendment to the claim is merely intended use language, and that the claimed "coupling system" merely needs to be capable of use with this type of syringe tube, which it is perfectly capable of being used with), wherein the coupling system comprises: a housing (16) for coupling to the tube of the syringe (the tube of the syringe is the tubular portion of 10); a drive mechanism disposed within the housing (34); a mixing member (24) for coupling to the drive mechanism, the mixing member extending into the tube of the syringe and being rotatable within the tube of the syringe in both the proximal portion and the distal portion (As noted above, the mixing member of the

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coupling system is perfectly capable of being rotatable in both a proximal and distal portion of the syringe. As disclosed in Fig. 1, the mixing member 24 extends within the tube of the syringe and rotates within the tube of the syringe. The examiner would like to point out that Applicant has not claimed that the mixing member must extend within the needle of the syringe, only into the *tube* of the syringe. As discussed above, Hicks meets this limitation) to mix and deliver an injectable from the tube of the syringe; and an actuator (30) coupled to the drive mechanism to actuate the drive mechanism and thereby cause rotation of the mixing member (21 couples the drive mechanism (34) to the mixing member (24) and the interfacing member (21) rotates which thus causes the mixing member (24) to rotate as well).

In reference to claim 19, Hicks discloses that the mixing member (24) is coupled to the drive mechanism (coupled to each other via interfacing member 21).

In reference to claim 20, Hicks discloses that the housing further comprises a mating portion (at 16), the mating portion being capable of mating with the tube of the syringe.

In reference to claim 22, Hicks discloses that the tube of the syringe comprises an injectable material (col. 3, lines 39-43).

In reference to claim 23, Hicks discloses that the housing comprises finger grips (40).

In reference to claims 28 and 29, Hicks discloses that the mixing member comprises a helical element (the contour of the mixing element is helical as it resembles a figure-8).

In reference to claim 30, Hicks discloses that the injector system comprises an injectable material comprising a shear-sensitive injectable material (please note that this component is part of the injector system which is part of the intended use phrasing of the claim and therefore the driving system merely has to be capable of use with it, which it is. Also, the reference discloses that the device is used to mix dental impression material which changes viscosity as it is mixed and is then subjected to shear forces when being injected through the needle, which therefore meets Applicant's definition of a shear sensitive material).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz-Feldman (US Patent No. 5,501,371) in view of Critchlow et al. (US

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2003/0171712). Schwartz-Feldman discloses the device substantially as claimed except for a low torque motor, a battery or a switch. Critchlow, however, discloses a hand-held syringe (Fig. 9) with a high speed, low torque motor (paragraph [0053]), that the motor is coupled to a battery as an energy source (paragraph [0046]) and that the actuator comprises a switch (paragraph [0128]). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Hicks with the specific motor, energy source and switch, as taught by Critchlow, in order to provide an injector system that is powerful enough to mix and inject such viscous material, as well as be hand-held and portable.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz-Feldman (US Patent No. 5,501,371) in view of Barker et al. (US Patent No. 6,033,105). Schwartz-Feldman discloses the device substantially as claimed except for the mixing member comprising a helical element. Barker, however, discloses a similar mixing device in which the mixing member comprises a helical element (Fig. 2, 30 for example). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Schwartz-Feldman with the helical element as taught by Barker, in order to provide a mixing member that both mixes the material and guides the material downwards toward the needle for subsequent injection. Furthermore, changing the mixing member to a helical member would require only a

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change in shape which is generally recognized as being within the level of ordinary skill in the art.

Response to Arguments

Applicant's arguments filed 5/14/2008 have been fully considered but they are not persuasive. As presented above, the amendments made the independent claims were made to the intended use clauses of the claims. Therefore the claimed "driving system" and "coupling system" of independent claims 11 and 18, respectively, merely need to be capable of use with the elements within the intended use clauses, which as presented above, the references are perfectly capable of doing.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767

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